

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	Mail Stop:
Peter KITE et al.)	APPEAL BRIEF - PATENTS
Application No.: 10/659,413)	Group Art Unit: 1617
Filed: September 10, 2003)	Examiner: Shobha Kantamneni
For: ANTISEPTIC COMPOSITIONS,)	Confirmation No.: 4621
METHODS AND SYSTEMS)	Appeal No.: 1

REPLY BRIEF

Mail Stop APPEAL BRIEF - PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Examiner's Answer issued 2 November 2006.

I. Status of Claims

Claims 32, 34, 37, 39, 41, 42, 45-47 and 55-60 are pending, rejected and presently appealed.

II. Grounds of Rejection to be Reviewed on Appeal

- 1) Claims 32, 34, 39, 41, 42, 45 and 55-60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Fahim (WO 00/13656) in view of Wider (U.S. Patent No. 6,500,861).
- 2) Claim 47 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Fahim (WO 00/13656) in view of Wider (U.S. Patent No. 6,500,861) and further in view of *Root et al* ("Inhibitory Effect of Disodium EDTA upon the Growth of *Staphylococcus epidermidis* In Vitro: Relation to Infection Prophylaxis of Hickman Catheters").
- 3) Claim 46 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Fahim (WO 00/13656) in view of Wider (U.S. Patent No. 6,500,861) and further in view of Remington's Pharmaceutical Sciences.

- 4) Claims 32, 34, 37, 41, 42, 45 and 55-60 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kurginski (GB 1 279 148) in view of Fahim (WO 00/13656) and Wider (U.S. Patent No. 6,500,861).

III. Argument

In the **Examiner's Answer**, on pages 9-18, the Examiner presents a *Response to Argument* section. The Examiner's responses are addressed below:

Response - Pages 10-12 of Examiner's Answer

The Examiner remarks:

One of ordinary skill in the art would have been motivated to prepare the antimicrobial composition of Fahim in a sterile and pyrogen free form with the expectation of success of employing the composition for ***eliminating infection*** from epidermis of the body because 1) Wider teaches antimicrobial compositions for eliminating infection on the epidermis of the body are ***effective when packaged in a sterile and pyrogen free form***, and 2) both Fahim and Wider teach that antimicrobial compositions therein are useful for eliminating an infection on the epidermis of the body.

Page 10, (emphasis added).

Further, the Examiner remarks:

Thus, Wilder [sic] teaches that the pyrogen free water provides the compositions therein to be effective for eliminating infection in general including the epidermis of the body of the user.

Page 12.

First, appellants assert that one skilled in the art would not use the antimicrobial composition of Fahim for eliminating infection. The Examiner appears to lose sight of the fact that the composition of Fahim is a handwash, a soap. It is not designed for or used to eliminate infection, and is instead used in a general cleansing, handwashing context. One skilled in the art would not put a handwash (soap) on an infected wound. Instead, the composition of Fahim is meant to reduce or eliminate bacteria on the surface of hands during routine hand-washing. See, e.g., page 2, lines 8-16. Killing bacteria during routine hand washing is significantly different from treating an infected wound. There appears to be too much focus on the term "antimicrobial composition" without a reasonable interpretation of the actual teaching of Fahim.

Second, appellants address the "effective when packaged in a sterile and pyrogen free form" language from the Examiner's Answer. As alleged in Wider, "This composition in concentrate form can be diluted or admixed with the deionized, pyrogen-free water to form an effective use solution." See Abstract. One skilled in the art would understand that the pyrogen-free water makes the solution *effective* for internal use, but does not have a specific bearing on the ability of the solution to eliminate infection.

That is, the Examiner appears to be confused about the function and meaning of the pyrogen-free water. The pyrogen-free water is a helpful component only for the uses on "internal spaces." The pyrogen-free water does not have a specific bearing on the antimicrobial nature of the solution. One skilled in the art understands that pyrogens are substances that induce fever. Thus, if a solution has pyrogens in it and the solution contacts a patient's bloodstream, then fever may result. Accordingly, a pyrogen-free solution is recommended for use in internal spaces to avoid causing complications by use of the solution.

However, the pyrogen-free nature of a solution has no specific bearing on the ability of the solution to eliminate infection or eliminate bacteria.

Thus, for external (epidermal) uses, the pyrogen-free nature of a solution is essentially meaningless.

Here, the Examiner is proposing to modify the handwash of Fahim to be in a sterile, pyrogen-free form as allegedly taught by Wider. But the composition of Fahim is simply meant to reduce or eliminate bacteria on the surface of hands during routine hand-washing. The pyrogen-free nature adds essentially no value to the handwash. Accordingly, one skilled in the art would not be motivated to modify the handwash composition to provide it in a sterile, pyrogen free form.

Response - Pages 12-13 of Examiner's Answer

The Examiner remarks:

Further, it is also pointed out that the intended use of a product or composition 'wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes', do not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art is capable of performing the intended use, then it meets the claim.

Page 13.

Appellants respectfully assert that the claim recitation "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes" must be given weight and does distinguish over the proposed modification of Fahim.

The Examiner has asserted that "If the prior art is capable of performing the intended use, then it meets the claim." Following the Examiner's assertion, if the prior art is *not* capable of performing the intended use, then it does *not* meet the claim.

The Examiner is asserting a proposed modification of Fahim: a sterile, pyrogen free handwash. One skilled in the art understands that a handwash (soap) would not be used for, and is not biocompatible with, in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes. This remains the same for a sterile, pyrogen free handwash. Needless to state, a handwash composition is specifically designed to cleanse intact skin surfaces.

Thus, there is a structural difference between the handwash (soap) of the Fahim and the presently claimed invention.

To simplify matters:

- Solution A is biocompatible in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes.
- Solution B is not biocompatible in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes.

There is a structural difference between solutions A and B. Thus, by the standard asserted by the Examiner the recitation at issue further limits the claim and further distinguishes the cited art.

Accordingly, the combination of Fahim and Wider would *not* result in appellants' claimed lock flush composition. There is no suggestion that any composition of Fahim, even if it were packaged in a sterile, non-pyrogenic form, would be biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes, as specified in claim 56. Thus, even if the combination

were made, the combination does not result in the lock flush composition specified in appellants' claim 56.

Response - Pages 13-14 of Examiner's Answer

The Examiner asserts that the compositions taught by Fahim will broadly encompass the instantly claimed limitation that the EDTA salt (claim 58) or the combination of tri- and tetra-sodium EDTA (claim 59) and provides at least 50% of a total antimicrobial activity of the composition.

The Examiner is reminded that Fahim relies on the three primary components (triclosan, PCMX and glutaraldehyde) for the antimicrobial activity of the composition. These are known and potent antimicrobials.

Thus, the Examiner has only identified that Fahim teaches the use of tetrasodium EDTA in combination with three known and potent primary components.

The Examiner has failed to consider the antimicrobial effects of the three primary components. Thus, the Examiner has not established a *prima facie* case that tetrasodium EDTA will provide at least 50% of the total antimicrobial activity in the composition of Fahim (triclosan, PCMX, glutaraldehyde and tetrasodium EDTA).

Response - Pages 14-15 of Examiner's Answer

The Examiner has maintained that one skilled in the art would be motivated by Root et al. to package the modified handwash of Fahim in a single dose vial.

Examiner again appears to lose sight of the fact that the composition of Fahim is a handwash, a soap. The proposed modification with Wider (while improper) is still a sterile, pyrogen free handwash.

Root et al. discloses the use of a di-sodium EDTA solution for inhibiting bacterial colonization in intravenous catheters.

The teachings of a solution used in intravenous catheters simply do not relate to a handwash solution. The teachings of a solution used in intravenous catheters would not motivate one skilled in the art regarding a handwash.

Further, appellants maintain that it would be absurd, unnecessary and prohibitively expensive to package the handwash composition of Fahim in a sterile condition in a single-dosage vial. Appellants submit that one of ordinary skill in the art would *not* be motivated by Root et al.'s use of sterile test tubes in experimental

protocols to package the antimicrobial handwash composition of Fahim in a sterile, non-pyrogenic form in a single-dosage vial.

Response - Page 15 of Examiner's Answer

The Examiner has maintained that one skilled in the art would be motivated by Remington's Pharmaceutical Sciences to package the modified handwash of Fahim in a prefilled syringe.

The Examiner once again appears to lose sight of the fact that the composition of Fahim is a handwash, a soap. The proposed modification with Wider (while improper) is still a sterile, pyrogen free **handwash**.

Remington's Pharmaceutical Sciences discloses the use of a **hypodermic syringe** to administer an electrolyte replenisher.

The teachings of an electrolyte replenisher used in hypodermic syringes simply do not relate to a handwash solution. The teachings of an electrolyte replenisher used in hypodermic syringes would not motivate one skilled in the art regarding a hand soap.

Reliance on Remington's Pharmaceutical Sciences to provide a teaching or motivation to provide the handwash composition of Fahim in a sterile, non-pyrogenic form in a pre-filled syringe is unfounded, is far outside the realm of obviousness, and could only be justified by improper resort to appellants' own specification and claims.

Response - Pages 16-17 of Examiner's Answer

The Examiner remarks:

Thus, one of ordinary skill in the art would have been motivated to pack the antimicrobial EDTA composition taught by Kurginski in a sterile, non-pyrogenic form with reasonable expectation of using the composition **to treat infections on epidermis**.

Page 17, (emphasis added).

This position is totally unreasonable. The composition of Kurginski is **toilet cleanser** -- a harsh toilet cleanser designed to treat and remove deposits derived from urine, fecal matter and rust. Further, the toilet cleanser "solubilizes for **almost effortless** removal the stone-like deposit from reaction of urine, dried closely adherent fecal matter, and gelatinous microorganisms." Page 2, lines 6-9.

The Examiner proposes that one would use such a solution to treat "infections" on the skin. This is not reasonable. A toilet cleanser that almost effortlessly removes toilet funk would not be used to treat infections on the skin (or, more accurately, "colonizations" on intact skin or "infections" in a wound). Thus, contrary to the Examiner's assertion, one skilled in the art would not have been motivated to package the toilet cleanser composition of Kurginski in a sterile, non-pyrogenic form for any purpose, much less with a reasonable expectation of using the composition to treat infections or colonizations on epidermis.

The Examiner's reliance on Kurginski is misplaced. Kurginski cannot be used as the Examiner has suggested to properly reject the pending claims.

IV. Conclusion

Appellants respectfully maintain that any of the Examiner's remarks not specifically addressed in this Reply Brief are not admitted. Appellants maintain that the Appeal Brief has adequately addressed these matters and appellants maintain the Appeal Brief.

Accordingly, appellants respectfully request that the rejection of claims 32, 34, 39, 41, 42, 45, and 55-60 under § 103(a) as being obvious over Fahim in view of Wider, be withdrawn.

Accordingly, the Examiner has not set forth a proper *prima facie* case of obviousness and appellants respectfully request that the rejection of claim 47 under § 103(a) as being obvious over Fahim in view of Wider and further in view of Root et al. be withdrawn.

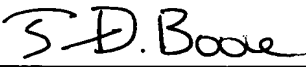
Accordingly, the Examiner has not set forth a proper *prima facie* case of obviousness and appellants respectfully request that the rejection of claim 46 under § 103(a) as being obvious over Fahim in view of Wider and further in view of Remington Pharmaceutical Sciences, be withdrawn.

Accordingly, appellants respectfully request that the rejection of claims 32, 34, 37, 41, 42, 45, and 55-60 under § 103(a) as being obvious over Kurginski in view of Fahim and in view of Wider, be withdrawn.

In view of the foregoing, further and favorable consideration of the pending claims in the form of a Notice of Allowance is respectfully requested.

Respectfully submitted,
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